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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,199	07/14/2003	Karin Jarverud	P03,0232	8711

26574 7590 03/14/2006

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EXAMINER	
PATEL, NATASHA	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,199	JARVERUD, KARIN	
	Examiner	Art Unit	
	Natasha N. Patel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 15-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *4-14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date [redacted]
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-3 and 15-22 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-4, 6, 8-11, and 13 of copending Application No. 10/432,970. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the explanations cited below.

2. This is a provisional obviousness-type double patenting rejection.

3. Regarding Claim 1, the co-pending application is, for the most part, equivalent in scope to the present invention. The co-pending application

discloses a monitor comprising: an impedance measurement unit (unit 9), an electrode arrangement (electrode 7), a notch detector (detecting means 6), and a pattern recognition unit (comparator 10). Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference to the detection of ischemia in the preamble is considered to be a statement of intended use lacking any further structural limitations in the body of the claim. Furthermore, the examiner considers that an impedance signal inherently includes a post-notch portion. Thus, all of the following steps applied to the impedance signal of the co-pending application would have automatically been applied to the post-notch portion discussed in this application.

4. Regarding Claim 2, the pattern recognition unit is equivalent, for the most part, to comparator 10 of the co-pending application (see Claim 3). Regarding the template comparison of the post-notch shape as opposed to the template comparison of the notch shape in the co-pending application, those of ordinary skill in the art would have considered the two comparisons to be essentially equivalent because the original comparison of an impedance signal to a template involves comparing all of the components of the signal, including the notch and post-notch shapes.

5. Regarding Claim 3, the differentiating unit is equivalent to the differentiating means 2 of the co-pending application (see Claim 3). Once again, the difference between the two inventions concerns which component of the impedance signal is focused upon. This difference is not patentably distinct as both the notch and post-notch are part of the impedance signal being compared

and the monitor is capable of performing either comparison. Furthermore, the examiner considers that comparing the impedance signal with the template would necessarily indicate deviations in time in addition to the deviations in shape.

6. Regarding Claim 15, Claim 1 of the co-pending application is equivalent in scope to the present invention. The co-pending application discloses an equivalent differentiating unit (differentiating means 2), loop generator (loop creator 5) and comparator (comparator 10).

7. Regarding Claim 16, Claim 3 of the co-pendng application is equivalent in scope to the present invention. Regarding the template comparison of a portion of the loop corresponding to the post-notch shape as opposed to the template comparison of a portion of the loop corresponding to the notch shape in the co-pending application, those of ordinary skill in the art would have considered the two comparisons to be essentially equivalent because the original comparison of the loop to a template involves comparing all portions of the loop, including the notch portion and the post-notch portion.

8. Regarding Claim 17, Claim 4 of the co-pending application is equivalent, for the most part, in scope to the present invention.

9. Regarding Claim 18, Claim 6 of the co-pending application is equivalent, for the most part, in scope to the present invention. Regarding the use of a pattern recognition unit as opposed to the use of a detecting means in the co-pending application, those of ordinary skill in the art would have considered the pattern recognition unit to be essentially equivalent to the detecting means

because the detection of a change is the result of performing a comparison of patterns. Thus, the pattern recognition unit is automatically detecting changes when it compares the average time derivative to the corresponding derivative template. Furthermore, the examiner considers the difference between disclosing an averaging unit in the present invention and a second averaging means in the co-pending application to be insignificant since both applications disclose that the first and second averaging units/means are formed by a single averaging unit/means.

10. Regarding Claim 19, Claims 4, 6, and 8 of the co-pending application are equivalent in scope to the present invention. The examiner considers the statement concerning detecting an ischemic heart disease to be functional language. The comparator of the co-pending application would be able to detect an ischemic heart disease as it has the same structural limitations as those disclosed by the present invention.

11. Regarding Claim 20, Claim 9 of the co-pending application is equivalent in scope to the present invention.

12. Regarding Claim 21, Claim 10 of the co-pending application is equivalent in scope to the present invention.

13. Regarding Claim 22, Claim 11 of the co-pending application is equivalent in scope to the present invention.

Claim Rejections - 35 USC § 103

14. Claims 1-3 and 15-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noren et al. (US Patent 5,427,112) in view of Jarverud et al.

15. Regarding Claim 1, Noren discloses an impedance measurement unit, including an electrode arrangement (see electrodes 102 and 107, col. 10, lines 29-32) for interacting with a patient to measure an intracardiac impedance and to generate a corresponding impedance signal (see Claim 1 and col. 1, lines 20-27). Noren also discloses a type of pattern recognition unit (see comparator, col. 4, lines 29-43), which compares the post-notch impedance curve with a stored reference impedance curve template to obtain a comparison result and to detect an ischemic heart disease from the comparison result (see col. 5, lines 41-52). The examiner considers that since Noren does a comparison analysis on the entire curve, then he is automatically comparing a post-notch impedance curve to the template being that the whole curve includes the post-notch curve. The examiner also considers the reference impedance curve template is equivalent to the predetermined curve of Noren's invention. Noren does not disclose the detection of a notch. Jarverud et al. discloses that the impedance notch might be a sensed feature of diagnostic value in their journal article "Analysis of the O-Wave In Acute Right Ventricular Apex Impedance Measurements With a Standard Pacing in Animals" (Med. Biol. Eng. Comput. 2002, Vol. 40, pgs. 512-519). One of ordinary skill in the art at the time of the invention would have thus found it obvious to focus on the notch due to its diagnostic value in detecting ischemic heart disease.

16. Regarding Claims 2 and 3, Noren discloses a pattern recognition unit (see comparator, col. 4, lines 29-43) that compares a shape of the post-notch impedance curve to a shape of the reference impedance curve template. Noren also discloses a differentiating unit (see differentiating circuit 123) that calculates the time derivative of at least the post-notch impedance curve, wherein the pattern recognition unit (see comparator, col. 4, lines 29-43) compares the shape of the time derivative of the post-notch curve with a stored reference time derivative curve template. The examiner considers that the entire signal is being compared to the reference and thus, the post-notch portion is automatically included in the comparison. Furthermore, the examiner considers arc length is a characteristic of shape. Thus, if there is a deviation in the arc length, there is also a deviation in shape.

17. Regarding Claim 15, Noren discloses a differentiating unit (differentiating circuit 123) supplied with an impedance signal for calculating a first time derivative of the impedance signal, a loop generator (RAM 126) connected to the impedance measurement unit and to the differentiating unit for plotting impedance values from the impedance signal relative to related values in the first time derivative to form a loop for each cardiac cycle, and a comparator (comparators 1-4) connected to the loop generator for comparing the loop with a loop template to obtain a comparison result for detecting an ischemic heart disease dependent on the comparison result (see col. 10, lines 41-66). The plotting of the impedance against the impedance derivative results in a loop as disclosed by Noren (see col. 2, line 68-col. 3, line 8).

18. Regarding Claim 16, Noren discloses that the comparator compares a shape of the loop in a portion of the loop corresponding to the post-notch impedance curve, with a corresponding portion of the loop template (see col. 10, lines 55-59).

19. Regarding Claim 17, Noren discloses an averaging unit (floating averager 226) connected to the impedance measuring unit for forming an average impedance signal from a plurality of impedance signals respectively obtained during a predetermined number of cardiac cycles (see col. 7, lines 21-23), and wherein the pattern recognition unit is connected to the averaging unit and compares a post-notch impedance curve in the average impedance signal with the reference impedance curve template (see Figures 13 and 20). The examiner considers the averaging unit is connected to the impedance measuring unit even though there are several signal processing elements in between the two. Similarly, the averaging unit is connected to the pattern recognition unit albeit indirectly.

20. Regarding Claim 18, Noren discloses a differentiating unit (differentiating circuit 123) supplied with the impedance signal that calculates a first time derivative of the impedance signal; an averaging unit (floating averager 126) connected to the differentiating unit which forms an average time derivative from a plurality of first time derivatives of respective impedance signals in a predetermined number of cardiac cycles (see col. 7, lines 21-23); and wherein the reference impedance curve template is a reference impedance derivative template (see col. 4, lines 35-43), and wherein the pattern recognition unit

(comparators 1-4) is connected to the averaging unit and compares the average time derivative of the post-notch impedance curve in the cardiac cycles with a corresponding portion of the reference impedance derivative template (see Figures 13 and 20). The examiner considers the respective comparison of the calculated arc length to a predetermined arc length means the impedance is compared to a respective impedance template and the impedance derivative is compared to a respective impedance derivative template.

21. Regarding Claim 19, Noren discloses a first averaging unit (floating averager 126) supplied with the impedance signal for determining an average impedance signal from a plurality of impedance signals measured during a predetermined number of cardiac cycles; a differentiating unit (differentiating circuit 123) supplied with the impedance signals that calculates a first time derivative of the impedance signals in the cardiac cycles, and a second averaging unit (floating averager 126) connected to the differentiating unit that forms an average time derivative from the respective first time derivatives in the cardiac cycles. Although Noren does not explicitly disclose a loop generator connected to the first averaging unit for plotting the average impedance values against related average time derivatives to form an average loop for each cardiac cycle, the examiner considers that RAM 227, to which the Z avg values and dZ/dt avg values are sent, is capable of doing the same loop generation as RAM 226 had done for Z and dZ/dt. Furthermore, Noren does not disclose a comparator that compares the average loop with a predetermined loop template to obtain a comparison result for detecting an ischemic heart disease dependent on the

comparison result. However, it would be obvious to one of ordinary skill in the art at the time of the invention to compare the averaged loops to templates since the original loops were compared to templates and the averaging step is simply an extra signal processing step aimed at eliminating motion artifacts and other noise. Finally, although Noren does not differentiate between a first and second averaging unit, the floating averager is capable of performing the functions of the first and second averaging unit, which are essentially one and the same entity.

22. Regarding Claim 20, Noren discloses an averaging unit (floating averager 126). Noren does not address the option of having two averaging units forming a single averaging unit. It would have been an obvious matter of design choice as to whether there is a single averaging unit used to average two different quantities, or two averaging units each separately used to average a single quantity. In either case, the results would be the same. Furthermore, having two averaging units would have been obvious to one of ordinary skill in the art at the time of the invention because it allows signals to be processed in parallel, eliminating the need to flip between signals and making analysis faster.

23. Regarding Claim 21, Noren discloses that the electrode arrangement comprises a bipolar ventricular electrode having an electrode tip and a ring, and wherein the impedance measuring unit measures the impedance signal between the electrode tip and the ring (see col. 12, lines 53-55).

24. Regarding Claim 22, Noren discloses a housing (pacemaker 140) containing the impedance measurement unit, the notch detector, and the pattern recognition unit, and wherein the electrode arrangement comprises a unipolar

ventricular electrode having an electrode tip, and wherein the impedance measuring unit measures the impedance signal between the electrode tip and the housing (see col. 11, lines 47-59).

Allowable Subject Matter

25. Claims 4-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NNP
3/6/2006

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